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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,177	10/05/2001	Laura C. Blumberg	PC11076A	3739

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT PAPER NUMBER

1624

DATE MAILED: 08/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/972,177

**Applicant(s)**

BLUMBERG ET AL.

**Examiner**

Brenda Coleman

**Art Unit**

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Claims 1-8 are pending in the application.

This action is in response to applicant's amendment filed May 13, 2004. Claims 1-8 were amended and claims 9-14 were canceled.

### *Response to Amendment*

Applicant's arguments filed May 13, 2004 have been fully considered with the following effect:

1. The applicants' amendments and remarks are sufficient to overcome the improper Markush rejection of claims 1-8 and 12-14 labeled paragraph 2) in the last office action, which is hereby **withdrawn**.
2. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 112, first paragraph rejection of claims 1-14, labeled paragraph 3) of the last office action, which is hereby **withdrawn**.
3. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 112, first paragraph rejection of claims 9-14, labeled paragraph 4) of the last office action, which is hereby **withdrawn**.
4. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 5) of the last office action, which are hereby **withdrawn**.

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In view of the amendment dated May 13, 2004, the following new grounds of rejection apply:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

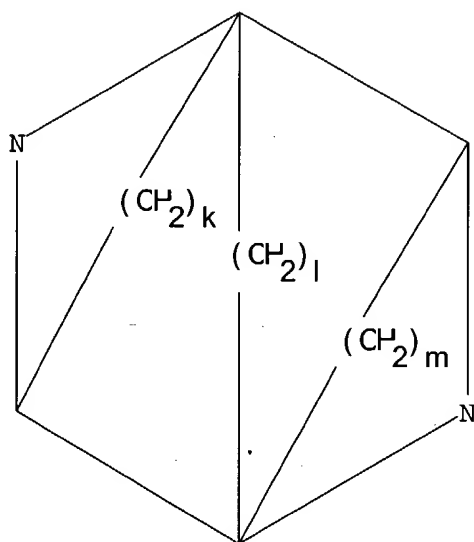
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-8 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

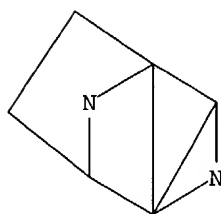
HOW TO MAKE: In evaluating the enablement question, several factors are to be considered. *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988); *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

The nature of the invention in the instant case, has claims which embrace compounds of the formula I, where k is 2, l is 0 and m is 0 in the formula

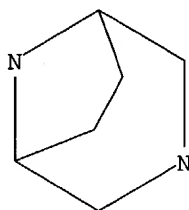
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The structure of formula I where k is 2, l is 0 and m is 0 would be as such:



not 3,8-diaza-bicyclo[3.2.1]oct-8-yl as shown below.



The compounds of formula I contain nodes within the structure labeled  $(CH_2)$  of which there are three. Each has two bonds joining the nodes. When k, l or m is zero, this indicates that there is no node between the bond and forms a direct link to the other two carbon atoms as shown above for the elected invention.

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The instant specification teaches 45 examples where W is N and k is 2, i.e. 3,8-diaza-bicyclo[3.2.1]oct-8-yl, 12 examples where W is N and m is 2, i.e. 3,8-diaza-bicyclo[3.2.1]oct-3-yl, 28 examples where W is C and k is 2, i.e. 8-aza-bicyclo[3.2.1]oct-8-yl, 1 example where W is N and l is 2, i.e. 2,5-diaza-bicyclo[2.2.2]oct-2-yl and 13 examples where W is N and k is 3, i.e. 3,9-diaza-bicyclo[3.3.1]non-9-yl. Each of these examples only possess one bridging moiety which is not depicted in formula I.

In view of the lack of direction provided in the specification regarding starting materials, the lack of working examples, and the general unpredictability of chemical reactions, it would take an undue amount of experimentation for one skilled in the art to make the claimed compounds and therefore practice the invention. To be enabling, the specification of a patent must teach those skilled in the art how to make and use the scope of the claimed invention without undue experimentation. The applicants' are not entitled to preempt the efforts of others. The test for determining compliance with 35 U.S.C. § 112, is whether the applicants have clearly defined their invention.

Claims 1-5 and 8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the definition of R<sup>5</sup> where R<sup>5</sup> includes the moieties carboxy(C<sub>1</sub>-C<sub>6</sub>)alkylaminocarbonylamino, (C<sub>2</sub>-C<sub>9</sub>)heteroarylaminocarbonylamino, ((C<sub>1</sub>-C<sub>6</sub>)alkylamino)(C<sub>6</sub>-C<sub>10</sub>)aryl(C<sub>1</sub>-C<sub>6</sub>)alkyl, amino(C<sub>1</sub>-C<sub>6</sub>)alkoxycarbonylamino, (C<sub>1</sub>-C<sub>6</sub>)alkyl, halo(C<sub>1</sub>-C<sub>6</sub>)alkyl, aminocarbonyl, ureido(C<sub>1</sub>-C<sub>6</sub>)alkylcarbonylamino, (C<sub>1</sub>-C<sub>6</sub>)alkylcarbonylamino(C<sub>1</sub>-C<sub>6</sub>)alkylcarbonylamino,

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(C<sub>1</sub>-C<sub>6</sub>)alkylcarbonylamino(C<sub>1</sub>-C<sub>6</sub>)alkylaminocarbonylamino is not described in the specification with respect to the genus of formula I.

Applicant is required to cancel the new matter in the reply to this Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 1-5 and 8 are vague and indefinite in that it is not known what is meant by the definition of R<sup>5</sup> where R<sup>5</sup> is the moiety cyano halo(C<sub>1</sub>-C<sub>6</sub>)alkoxy. See page 8, line 17.
- b) Claim 5 recites the limitation "CH" in the definition of W. There is insufficient antecedent basis for this limitation in the claim.
- c) Claim 5 recites the limitation "3" in the definition of k. There is insufficient antecedent basis for this limitation in the claim.
- d) Claim 5 recites the limitation "zero, zero and 2 or 3 respectively" in the definition of k, l, and m. There is insufficient antecedent basis for this limitation in the claim.
- e) Claim 6 is vague and indefinite in that it is not known what is meant by the second occurrence of (C<sub>2</sub>-C<sub>9</sub>)heteroaryl amino, which appears in line 5 of the claim and again in line 6 of page 13.

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- f) Claim 6 is vague and indefinite in that it is not known what is meant by the second occurrence of  $((C_1-C_6)alkyl)_2amino(C_1-C_6)alkylcarbonylamino$ , which appears in line 17 of the claim and again in lines 8-9 of page 13.
- g) Claim 6 recites the limitation "amino( $C_1-C_6$ )alkoxycarbonylamino" in the definition of  $R^5$ . There is insufficient antecedent basis for this limitation in the claim. See line 4 on page 13.
- h) Claim 7 is vague and indefinite in that it is not known what is meant by the second occurrence of  $(C_2-C_9)heteroaryl$ amino, which appears in line 5 of the claim and again in line 17 of page 14.
- i) Claim 7 is vague and indefinite in that it is not known what is meant by the second occurrence of  $((C_1-C_6)alkyl)_2amino(C_1-C_6)alkylcarbonylamino$ , which appears in line 6 and again in lines 19-20 of page 14.
- j) Claim 7 recites the limitation "amino( $C_1-C_6$ )alkoxycarbonylamino" in the definition of  $R^5$ . There is insufficient antecedent basis for this limitation in the claim. See line 15 on page 14.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Brenda Coleman  
Primary Examiner Art Unit 1624  
August 27, 2004